K051361

JUN 16 2005

# Summary of Safety and Effectiveness

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|---|---|
| **General Provisions** | **Trade Name**: Easy Core™ Detachable Biopsy System<br><br>**Classification Name:** Biopsy System, Gastroenterology-urology |
| **Name of Predicate Devices** | Easy Core™ Biopsy System, Easy Core Biopsy System II, ASAP Biopsy System (Formerly referred to as Stamey Sampler Spring Loaded Needle), ASAP 14g Biopsy System. |
| **Classification** | Class II |
| **Performance Standards** | Performance Standards have not been established by FDA under Section 514 of the Food, Drug and Cosmetic Act |
| **Intended Use and Device Description** | The Easy Core Detachable Biopsy System is indicated for use endoscopically or percutaneously to retrieve tissue sampling of soft organs/tumors or masses for histological analysis. Soft tissue sampling includes but is not limited to organs such as breast, liver, kidney and prostate. The Easy Core Biopsy System is a sterile, single-use biopsy needle. |
| **Biocompatibility** | The Easy Core Detachable Biopsy System has been tested for biocompatibility per ISO 10993. All data demonstrate this device is biocompatible for its intended use. |
| **Summary of Substantial Equivalence** | The Easy Core Detachable Biopsy System has been tested and compared to the predicate device. All data gathered demonstrate this device as substantially equivalent. No new issues of safety or efficacy have been raised. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 16 2005

Ms. Christine M. Cameron
Regulatory Specialist
Boston Scientific Corporation
Oncology Division
100 Fairbanks Blvd.
MARLBOROUGH MA 01752-1242

Re: K051361
Trade/Device Name: Easy Core™ Detachable Biopsy System
Regulation Number: 21 CFR §876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: KNW and FCG
Dated: May 24, 2005
Received: May 25, 2005

Dear Ms. Cameron:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

| | | |
|---|---|---|
| 21 CFR 876.xxxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 892.xxxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications For Use

**510(k) Number (if known)** ~~Unknown~~ K051361

**Device Name:** Easy Core™ Detachable Biopsy System

**Indications for Use** The Easy Core Detachable Biopsy System is indicated for use endoscopically or percutaneously to retrieve tissue sampling of soft organs/tumors or masses for histological analysis. Soft tissue sampling includes but is not limited to organs such as breast, liver, kidney and prostate.

Prescription Use ✓ ~~AND/OR~~ Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K051361